NABC7 : A *Synthesis and Challenge*

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There have been many good discussions throughout this meeting, and some very good speakers have made targeted comments that brought out the breadth of the issues involved. The workshop sessions have been good and there were fascinating individual conversations over meals. It is a tall order for me to try to pull this wealth of interaction together. I have decided to go back to what the organizers cleverly came up with originally — Discovery, Ownership and Access. I want to talk about some issues I see in those areas, and then at the end bring out some synthetic points or challenges that I see. My only reservation in talking about Discovery, Ownership and Access is that, as I was writing myself notes, 1 saw that the initials are D-O-A, possibly not a good omen.

Discovery

In *Discovery,* some of the questions to be asked are: Who discovers? With what purpose? How is the discovery process funded, and in what context does it take place? A key issue in discovery, of course, lies in the health and well-being of research, the discovery process in particular. As Dick Flavell described so well in the opening session, the pace of discovery related to genes is accelerating rapidly. The sharing of useful information that we have been doing in this meeting is just one example. Maybe we will find out more about minor crops or developing country crops as we learn about major crops. The prospects are very exciting. Breeders may exchange information more readily. There may be a real explosion of both knowledge and ability to implement. Ron Sederoff described the example of mapping the loblolly pine that would have been impossible two years ago and unthinkable ten years ago, but now it is being done. The question is: Will this pace continue? Will it accelerate? Or will it slow down due to obstacles or to costs exacted by intellectual property rights and the standard operating procedure of our university/industry/government interface as it exists today?

We also heard some examples of work that is not going to be done. Forest tree genetics-environment interaction on a large scale is fundamental work that will not be done because of cost. Many issues exist that are fundamental to research policy, and many working papers have made recommendations accordingly. Can we develop and implement research policy that will protect discovery in agricultural biotechnology? The recommendations from the workshops tend to center on: ensuring the survival of long-term basic research and somehow inserting social responsibility into the agenda-setting process, facilitating discoveries that will ultimately benefit the public.

Ownership

In *Ownership*, some of the questions to be asked are: Who owns what? What is the "what" that is being owned? What are the overriding traditional principles governing ownership, and are there any new paradigms for principles to govern ownership? Are there new opportunities for sharing? In whose best interest are ownership practices right now? Is the public benefiting and is there equitable treatment? A central need in ownership is to address what often appears to be the conflict between social good and private gain. That dynamic tension has come up over and over again and will continue.

There is a whole cluster of concerns over possible negative impacts of ownership on universities or on the research enterprise. Kathleen Merrigan, Ron Sederoff, Jack Tribble, Leanna Lamola and others raised relevant questions. Are we going to skew the agenda for what research is done? If we move towards shorter term research, or research that fits with private sector gain or that is shaped by consideration of intellectual property rights, are we using up our intellectual capital? We have been building useful discoveries on the basic work that has been done in the past; what do we do when we run out of such research results? Similar questions arise in education. Are there conflict of interest problems? What is the cost of not doing other kinds of research? Lamola brought up commodity groups' questioning of intellectual property rights. Those groups have always questioned some of our newer technology transfer approaches. It is an old controversy, but maybe there are some new lessons to be learned.

A key issue is the ownership system and the universality of its appropriateness. Merrigan asked why we are so anxious to have all developing countries blindly take on our technology transfer/intellectual property rights system. Jose Luis Solleiro pointed out significant differences between the U.S. and developing countries. For example, developing countries face different kinds of markets, domestic industry, research strengths and governmental priorities. The interface between the U.S. system arid intellectual property systems that are operational in other countries needs to be looked at. What can be done to make such an interface work? What kinds of understandings and partnerships do we need to reach?

Another issue close to the heart of ownership is valuation. How would you sort out the proportion of value added by an inserted gene from a plant found in a developing country placed into a plant variety originally developed in a long-term breeding program at a public institution supported by public U.S. funds? Where is the incremental value? Where is the proportionality? John Kinsman and Solleiro both talked about this. How do you put a proportional value on knowledge? Today in agricultural biotechnology we are making the necessary move toward an approach of putting different pieces of knowledge together — which is crucial to forward movement — but how do you sort out ownership, credit and compensation? Compensation issues are key to ownership.

And, finally, and quite basic to the theme of ownership, what is covered by a patent? What is a novel gene? As we learn more about similarities among different species, how different do sequences have to be to be patentable? What is the appropriate breadth of a patent? 1 was told by a CEO of an agricultural biotechnology company a few days ago, when he heard 1 was to make this presentation, "Make sure to tell them that we have to have broad patents, or else there's no incentive for industry." And what we heard at this meeting was: "Be sure you have narrow patents so there's incentive for everybody." There is some lively controversy there. The scope of patentability and ownership is especially important when you consider, as Lamola discussed, the identity preserved systems or other systems when at any point in the whole, complex process of production, upstream or downstream, there might be some "moment" of intellectual property protection that will have an impact on the rest of the whole stream. Is that a strength or a vulnerability, and what are the implications? We have heard recommendations spanning the wide spectrum of "do not challenge the patent system, it works" to "do away with the patent system."

Again, there are interesting differences in points of view. Clearly, it seems what everybody wants is some examination of intellectual property rights related to genes, related to agricultural biotechnology, and related more broadly to the public good. This is going to entail looking closely at public-private interfaces and different roles of different institutions. There were some recommendations about that and about roles that the NABC might play as well. Another thought that surfaces is that distribution of profits and benefits should be equitable, whatever that truly means. One workshop group suggested that there will not be one easy answer; instead, the best distribution is probably going to be based on people coming together and negotiating what is equitable. That is probably true on a variety of levels.

Access

As far as *Access:* Who has access to what? What traditional principles guide us in access? Is there a need for new principles? Can we go further in making access equitable? Can we maximize the public good through approaches to

access? Access can refer to researchers, research tools, and in some sense it can also refer to the public's access to the products ultimately arising from research. That last idea is a worthwhile sub-theme to keep in mind. Obviously, one of the big points that caught on and was phrased in many different ways by the workshop participants is some sort of "research exemption." That seems to have struck a real chord. However it is phrased or however it is implemented, that idea of preserving freedom of inquiry and investigation and curiosity-driven research in our institutions is important, even knowing that our institutions also engage in technology transfer. Preserving that capability seems to be one of the heartfelt responses of the conference. The NABC may well have a role in clarifying that situation, as well as specifics on materials transfer agreements and other agreements. The Association of University Technology Managers (AUTM) has clearly done a great deal in this area, and there seems to be a useful role for using the NABC as a dissemination vehicle.

Another issue, as Peter Day discussed from firsthand experience, is the sheer growing complexity of gene ownership. There are difficulties in access for research purposes and product development. If you have a gene, a vector, a promoter and an original cultivar all from different sources, are the university technology transfer offices ready to handle this? Is it just so mind boggling that it should stop you from doing research at the start? Do you need to start doing research and hope that you can hand it off to a company with a large regulatory staff to sort it all out later? Some kind of clarification up front is probably going to be necessary. But if we wait for a perfect, extensively legal clarification at the beginning we might not ever get going and do the research. The question of access is an important one.

A related access issue arises in business decision-making. As Day talked about, in some cases, such as the development of minor crops, the public may be a victim of cold, hard business strategies. If a company is focusing only on top-priority opportunities it may close down access to genes important for minor crops or for what seems to be a tangential opportunity. In fact, access to the genes might really serve some particular public component. How can we ensure that the public benefits in a wide array of ways through access to discoveries?

In relation to the access issue of management of information from genome sequencing, Flavell mentioned that the patenting of genes is very likely to inhibit the free global flow of germplasm. How are people going to handle this? How is information going to be handled? Are people going to slip things under the table, or are they going to have mammoth exchange agreements? How can exchange of information be facilitated? Tribble mentioned that the Bayh-Dole Act intended to make information available, and yet somehow that is not happening. The effect is the opposite. Merck & Co., Inc. is trying an interesting experiment by making materials available for research tools separate from licensing for products. That kind of distinction may be a very useful one.

That there is this wildly complex system within the U.S. is not enough. The complexity across international borders also needs to be tackled. It was addressed as the North-South issue in many of the workshop discussions and background presentations. Henry Shands, Merrigan, Solleiro and others discussed this in relation to the Biodiversity Convention and other frameworks. Clearly, genetic resources from around the world are going to be crucial to future progress in agricultural biotechnology. But how should farmers' rights be handled? Shands pointed out that, in the convention, parties are to endeavor to create conditions to facilitate access to genetic resources through: mutually agreed upon terms, prior informed consent, and sharing of benefits in a way that is clear up front. Those are not bad principles to live by in a variety of situations. If those criteria are reduced to practical human terms, it may actually be possible to make things work.

Solleiro also made an important distinction by noting that free access does not necessarily mean "free of cost" or "free of charge." Equitable compensation issues are related to access issues. He offered a challenging question: "How do you translate moral recognition into an economic reward?"

Recommendations were presented regarding access in some equitable form: access to genes, to technology, to information; access for researchers, university, industry, government, farmers and consumers, the ultimate beneficiaries of products. Many recommendations on something like a research exemption were presented, as were recommendations on education so that people have a voice in decision-making with input into research agendas and a role in shaping policy. Again, this all comes back to the theme of benefiting the public good. There was also a strong recommendation to work with and empower Third World farmers and indigenous peoples and countries to recapture some equitable compensation for their genetic material.

A Few Thoughts

Now that I have given a quick summary, 1 would like to offer a few thoughts that synthesize a little bit and leave you with a couple of challenges. Why do we care about genes and ownership and access and discovery? 1 think the answer is that at some level we are thinking about the public good. What are our public goals? Growth of knowledge, economic development, and a variety of benefits to a variety of publics. It seems to me that to achieve those goals, we are going to need a thriving interrelationship among discovery, ownership and access. We are going to have to optimize each, and they will be optimized more completely if each works well with the others. You can look at discovery as the engine of innovation, though I am a little worried that we are using up our fuel of past intellectual capital. The institutions that tend to drive discoveries are under pressure to take ownership, to deal with technology transfer offices and to bring in money. But they are also under pressure to provide easier access to what they discover; many are land-grant institutions with a traditional mission

of serving the public. There are some interesting, competing pressures in the discovery process.

Ownership drives commercialization. I think many people would argue that without ownership there is no incentive for companies to make products that will ultimately benefit society. Can we help self-interest become enlightened self-interest?

If discovery is the engine and ownership drives the engine, then access may be like public transit, with ideals of democracy, efficiency and equitability. Obviously, access is necessary for discovery; discovery is necessary for ownership and for access; and ownership is probably necessary in a capitalist system for the public's access to products. We are going to need healthy discovery and equitable access, yet the tricky part is the conjunction of ownership and access. Where do you benefit access at the cost of ownership and vice versa? How do you achieve that balance? As Merrigan brought up at the beginning, it is often a good idea to question even our fundamental premises. Do we need the current intellectual property system? Do we need a new paradigm? We had recommendations that NABC or others re-evaluate intellectual property rights related to agricultural biotechnology in order to make sure that we are moving towards the public good, and we asked many specific questions on patent scope and technology transfer and so on. Maybe it is useful to look at developing countries that do not have our overall system in place. I talked to someone at the National Academy of Sciences who worked with Pakistan to help that country put a technology transfer system into place, moving through various stages as a country that had not had intellectual property protection in the past. Looking at a country without our system is an opportunity to take a fresh look at why or how we do things. As we work with other countries, we can gain new perspectives on the possibilities.

One aspect of a fundamentally new paradigm, and nobody mentioned this that 1 heard, are the religious groups that are coalescing, to some degree or another, against the patenting of human and animal genes as described in a *New York Times* article in mid-May, 1995. I talked with Paul Thompson, an ethicist from Texas A&M University, a NABC member institution, who has talked with people involved who actually reflect a wide variety of motivations. One religious group may be against patenting human and animal genes for one reason, perhaps views of appropriate scope of laws of nature, while another group may be against it from a fundamentalist point of view. Yet, all these religious bodies are coming together, not for famine or war, but for biotechnology and patenting issues. In Europe, there are questions about patenting body parts and whether or not that includes DNA sequences in genes. This social and ethical dimension, which ties into education and the importance of listening to a variety of points of view, really needs to be part of the discussion, or part of our paradigm. There are some real challenges here.

One clear theme that came out all though the talks is that change is happening. The role of land-grant universities and other institutions is changing and will continue to change. The Kellogg Foundation has funded a series of 12 projects to: help land-grant universities talk to their constituencies; find out what these stakeholders want the world to be like in 2020; and figure out how the universities need to change fundamentally as institutions to help their constituencies reach that "vision." Since the world is changing and the role of land-grant universities and other institutions is going to change anyway, do we want to float along with it or do we want to help shape the change? That is a central challenge facing us in regard to the topic of this meeting.

New Partnerships

One approach to addressing this challenge is to think about forming new partnerships. We have looked at the different roles of the private and public sectors. Maybe we can put partnerships together in new ways. That will mean change, issues, stress and complexity, but just maybe it is worth working through that. We have heard that the picture is not bright for research funding. That there is not a sugar daddy of federal funding out there waiting for us. We will need to get all the leverage we can and figure out how each player can complement what the other is doing. Yet in building partnerships, we have to be careful about some things such as long-term research. 1 was talking with Dick Flavell earlier, and we discussed the fact that many times when partnerships are formed they are formed for some specific purpose, and that specific purpose is likely to be short-term. This is often true of the standard university/industry contract. We may need to form special partnerships with some mutual education paying specific attention to long-term research and exploration.

John Kinsman, a Wisconsin farmer, told us that we need "constructive cooperation" rather than "deadly competition," and I think that is true on many different levels. We have instructive examples of partnership building to consider. Merck has facilitated university, government and industry people working together to set up a database of human cDNA sequence fragments. That is one example. While it is not something to slavishly copy at all times, it is an example of people getting together to grapple with some of these issues. In Europe, there is a yeast sequencing center, a consortium where information is disseminated and shared, even though there are opportunities to patent. Again, this demonstrates that effective and innovative partnerships can be formed. We want to protect the essential, long-term effort of investigation and discovery we make at our institutions. We want to somehow nurture partnerships and "mutual responsibilities," as was said in one of the workshops. The concept of mutual responsibilities among universities, industry and government to maintain vision and mission provides a useful framework for action, 1 believe.

The Challenge

As a group, we have generated a good many recommendations. I hope that we will think about them, that we will engage others in conversation about them, and maybe even that we will pursue some of those action steps. I suspect that there is no one solution, no one thing that needs doing. I am going back to Flavell's launching of the meeting when he talked about how, as the head of an institute, he plays as many threads as he can to try to make sure the public benefits. Sometimes that means handing intellectual property out for free, sometimes it means non-exclusive licenses, and sometimes it means exclusive licenses. Pursuing several different possibilities, as appropriate, can maximize the chance of success. More broadly, I think we are going to have to pursue several approaches as we work our way through intellectual property rights and genes, and discovery, ownership and access issues, looking for ways in which agricultural biotechnology can be of benefit to the public. The task of identifying appropriate approaches to addressing our challenges is helped immensely by the dialogue we have enjoyed throughout this meeting as people with different perspectives have come together, wrestled with tough issues and worked to come up with implementable action steps.